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Atty. Dkt. No. 029488-0113

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Philippe ROUANET et al.  
Title: PREVENTION AND TREATMENT OF BREAST CANCER  
WITH 4-HYDROXY TAMOXIFEN  
Appl. No.: 10/734,638  
Filing Date: 12/15/2003  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. As a courtesy, copies of these types of documents are being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language counterpart of the foreign-language document has not been provided. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

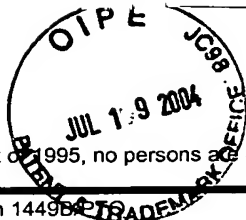
Respectfully submitted,

Date 16 July 2004

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Substitute for form 1449B-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: July 19, 2004

(use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	10/734,638
Filing Date	12/15/2003
First Named Inventor	Philippe ROUANET et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	029488-0113

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,973,755		Heumann Pharma GmbH & Co.	11/27/1990	
	A2	4,919,937		Pierre MAUVAIS-JARVIS et al.	4/24/1990	
	A3	5,904,930		Hexal AG	5/18/1999	
	A4	5,945,109		s.w. Patentverwertungs Ges.m.b.H.	8/31/1999	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A5	International Search Report	
	A6	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research, Vol. 46, 3/1986, pp. 1521-1525.	
	A7	F. KUTTENN et al., "Principe de l'administration percutanée des antiestrogènes en pathologie mammaire", Contracept. Fertil. Sex. 1991, Vol. 19, No. 2, pp. 165-171.	
	A8	I. Simony-Lafontaine et al., "NEOADJUVANT PERCUTANEOUS-4-HYDROXYTAMOXIFEN DECREASES BREAST CANCER CELL PROLIFERATION: A PROSPECTIVE RANDOMIZED IMAGE ANALYSIS STUDY", Analytical Cellular Pathology, vol. 25, no. 5-6 2003, pp. 258-259, XP009030125.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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